### UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

| IN RE PHARMACEUTICAL INDUSTRY<br>AVERAGE WHOLESALE PRICE<br>LITIGATION | )<br>)    | L No. 1456<br>I Action No. 01-12257-I | DRS |
|--|-----------|---------------------------------------|-----|
|  | ) Civii   | i Acuoii No. 01-12237-i               | : D |
| THIS DOCUMENT RELATES TO:  | )<br>Judg | e Patti B. Saris                      |     |
| State of Arizona v. Abbott Labs, et al.                                | )         |                                       |     |
| 06-CV-11069-PBS  | )         |                                       |     |
|  | )         |                                       |     |

## MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

#### PRELIMINARY STATEMENT

The time has come for the over seven years of fact development and legal analysis in this consolidated AWP MDL proceeding to serve as a basis on which to evaluate the plausibility of certain claims and actions, and to put an end to those that fail to meet the test for pleading announced by the Supreme Court in *Bell Atlantic Corp.* v. *Twombly*, \_\_\_ U.S. \_\_\_, 127 S. Ct. 1955, 1965-67 (2007). The State of Arizona's case is one such action. Arizona's First Amended Complaint ("Complaint") abandons all claims for recovery on behalf of the State's Medicaid program and, instead, asserts claims only on behalf of private citizens and other payors for violations of Arizona state law. (*See* Arizona's Mem. in Supp. of Mot. for Protective Order ("Protective Order Mem."), at 1 (June 13, 2008) (Dkt. 5378).) In fact, in a recent filing, Plaintiff went so far as to argue that "[n]either the State nor the agencies . . . have claims in the case," that "the government is not even a party" to this action, and that "neither the government nor any governmental agency brings a claim." (Protective Order Mem. at 4, 8.). But, this hardly cures the First Amended Complaint of its overbreadth and implausibility.

To the contrary, the State of Arizona purports to bring a "mini-MDL class action" proceeding. The First Amended Complaint, consisting of 186 pages and an Appendix A, asserts a single count under the Arizona Consumer Fraud Statute, A.R.S. §§ 44-1521, et seq., for injunctive relief, penalties, and restitution sought on behalf of Third Party Payors ("TPP"), individual consumers, and Medicare beneficiaries resident in Arizona. (See Compl. ¶ 514.) It seeks recovery with respect to every imaginable category of drugs: self-administered drugs ("SADs") and physician-administered drugs ("PADs"); brands and multi-source drugs; and every combination and permutation thereof. It seeks recovery for every private payment, insurance reimbursement, or Medicare co-payment made for the more than 1,000 drugs listed in Appendix A over an unspecified number of years, likely comprising millions and millions of transactions. And, it does so without any of the particularity necessary to make these claims plausible or even manageable for this Court.

In a move reminiscent of the movie *Groundhog Day*, Plaintiff attempts to pursue these vast categories of claims despite this Court's prior rulings in, and the significant overlap with, the MDL class action proceeding. As Exhibit 1 to this Memorandum illustrates, this Court's prior rulings highlight the particular implausibility of many of these categories of claims, while settlements and judgments bar other whole categories of claims:

- Self-Administered Drugs This Court declined, for example, to certify a class as to SADs in the private marketplace, finding that, because of the extensive role played by Pharmacy Benefit Managers ("PBMs"), knowledge about the "spreads" between AWP and acquisition cost for self-administered drugs was pervasive in the marketplace and that such knowledge was pro-competitive. The Court also noted in its ruling on the Track 1 trial that, for brand SADs in particular, no plausible motive exists for manipulating reported prices because the prescribing function is separate from the dispensing/reimbursement process.
- Multi-Source Drugs (whether SADs or PADs) Similarly, this Court concluded in the MDL class action proceeding that, because of the extensive use of MACs in reimbursing for multi-source drugs in the private market, for plaintiffs to proceed with multi-source claims, they must expressly identify which reimbursements were based on AWP. In light of this entirely reasonable requirement, class plaintiffs (represented by the same counsel

as the State of Arizona) choose to abandon these claims completely as to Class 3 in the MDL, admitting that, within "six months after the first generic launch," MACs are so widely used that it is not possible to "calculate damages." As to Medicare claims, this Court has recognized that Medicare's use of a median to reimburse for multi-source drugs leads to "almost intractable causation issues."

• Settlements and Judgments – All of the Track Two defendants and some Track One defendants have reached wide-ranging, nationwide settlements with various classes of TPPs, individual consumers, and Medicare beneficiaries, covering a wide variety of drugs. Other Track One defendants won verdicts in their favor that are now final. Certainly these settlements and judgments are binding on at least some (if not all) Arizona TPPs, consumers, and Medicaid beneficiaries.

And, this list of problems is just the beginning. Exhibit 1 and the memorandum that follows details each of these issues and others, as they relate to each of the categories of claims that the State of Arizona purports to bring, and ultimately highlights precisely why this Complaint must be dismissed.

Such discredited allegations of "fraud," unsupported by a factual context that would make them plausible, must be dismissed with prejudice in accordance with *Bell Atlantic Corp.* v. *Twombly*, \_\_ U.S. \_\_, 127 S. Ct. 1955, 1965-67 (2007). Moreover, claims that are purportedly being brought on behalf of individuals and TPPs who have settled those claims and claims that are being brought on behalf individuals and TPPs who have had them adjudicated as members of a class in the MDL Class Action are barred. *See*, *e.g.*, *In re Bridgestone/Firestone*, *Inc. Tire Prods. Liab. Litig.*, 333 F.3d 763 (7th Cir. 2003); *In re Baldwin-United Corp.*, 770 F.2d 328 (2d Cir. 1985). Plaintiffs' claims should also be dismissed as untimely. *See* A.R.S. § 12-541. They cannot be revived simply because they are now being brought again in a slightly different form by the State of Arizona purportedly in a "representative" capacity. *See In re Baldwin-United Corp.*, 770 F.2d at 328.

In short, there are vast categories of claims (maybe all of them) that should be dismissed with prejudice and, after seven years of litigation, should stay dismissed – without leave to replead. Furthermore, if Plaintiff is going to proceed with any claims, much more particularity is

required. It should not be up to the Court (or defendants for that matter) to parse through the various categories of claims made, and the more than 1,000 drugs listed in Appendix A (without any spreads), to decide what is in and what is out. At the very minimum, the present Complaint should be dismissed in its entirety, and before Plaintiff is allowed to proceed with this case, it should be required to plead with particularity which categories of claims remain viable, specify the facts that make those categories of claims plausible, identify the drugs that they say fall into each category of claims, and allege "spreads" for each such drug. *Twombly*, Rule 9(b), and this Court's prior rulings and its inherent authority to manage this litigation require nothing less.

#### **ARGUMENT**

I. PLAINTIFF'S CLAIMS REGARDING SELF-ADMINISTERED DRUGS AND BRAND SELF-ADMINISTERED DRUGS IN PARTICULAR, GENERIC DRUGS SUBJECT TO A SINGLE REIMBURSEMENT RATE, BRANDS WITH UNREMARKABLE WAC/AWP SPREADS, AND CLAIMS MADE AFTER THE PASSAGE OF THE MMA SHOULD BE DISMISSED AS IMPLAUSIBLE.

As this Court has recognized, *Twombly* is now the pleading standard. "In order to survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6), a plaintiff's complaint must allege 'a plausible entitlement to relief." *New England Carpenters Health Benefit Fund* v. *McKesson Corp.*, C.A. No. 07-12277-PBS, 2008 WL 3919121, \*1 (D. Mass. Aug. 26, 2008)(Saris, J.) (citing *In re Citigroup, Inc.*, Nos. 06-2565, 07-11502008, 2008 WL 2840601, at \*4 (1st Cir. July 24, 2008). To warrant extensive discovery and impose the often significant cost of litigation, the Supreme Court held that a plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." *Twombly*, 127 S. Ct. at 1974 (emphasis added). Plaintiff's claims with respect to self-administered drugs, multi-source drugs, and certain other claims fail the plausibility standard announced by the Supreme Court in *Twombly* and should therefore be dismissed pursuant to Rule 12(b)(6).

In light of this Court's prior rulings, Plaintiff's logic is even more flawed here than in Twombly. Plaintiff's claims regarding self-administered drugs are implausible in light of the important role that this Court has recognized PBMs play in the marketplace for SADs. Even more implausible, though, are Plaintiff's claims with regard to brand, self-administered drugs for which the dichotomy between the person who prescribes them – the physician – and the person who dispenses them – the pharmacist – renders any allegations of motive completely illogical. These allegations are unaccompanied by any factual context that would make them intelligible. The single rate paid to reimburse all versions of most multi-source drugs – whether a MAC, a median, a FUL or other – is likewise incongruous with the motivation alleged for the implausible "AWP fraud" scheme posited by Plaintiff – winning market share from competitors by manipulating reported prices – and likewise commands dismissal of those claims. Similarly, Plaintiff's theory of "AWP fraud" cannot be sustained as to any drugs whose spreads are 30% or less because, as this Court has found, such spreads are not indicative of fraud or deception. Nor can Plaintiff prevail with regard to payments and co-payments made after the passage of the Medicare Modernization Act of 2003 (the "MMA"). These implausible claims should be dismissed with prejudice in accordance with the Supreme Court's holding in Twombly and Rule 12(b)(6).

### A. Plaintiff's Claims with Regard to SADs are Facially Implausible and Should Be Dismissed.

Contrary to *Twombly*, Plaintiff has not alleged facts to make plausible its facially incredible claims to relief with respect to SADs in the private market. The role of Pharmacy Benefit Managers ("PBMs") in the SAD market renders implausible any claims of fraud or deception with respect to payments or co-payments that TPPs and individuals made for SADs. PBMs, through whom the vast majority of reimbursements for SADs are channeled, give their insurance clients (TPPs) and insureds the benefits of superior knowledge and rebates from

manufacturers. PBMs are savvy market participants whose knowledge of the market's operation is incongruous with the Plaintiff's allegations of deception, fraud, and injury. Thus, this Court in the MDL Class Action declined to certify a class with respect to SAD-based "AWP fraud" claims because it found that the knowledge and roles of PBMs in the SAD market precluded class-wide claims affecting that market. *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 230 F.R.D. 61, 95-96 (D. Mass. 2005) (hereinafter "Class Certification Opinion"). In so ruling, the Court reasoned that the structure of the SAD market – particularly the presence of PBMs and Maximum Allowable Cost ("MAC") reimbursement – undermined the logic of plaintiffs' allegations. So too here.

PBM's knowledge and experience preclude any claim of deception or fraud affecting an insurer or managed care organization who used the services of a PBM and any individual who was covered by such an insurer or managed care organization. AWPs – even if they were inflated (as Plaintiff alleges) – did not deceive any such consumer. In its *Class Certification Opinion*, this Court discussed at length the dominant role that PBMs play in the reimbursement for SADs, calling them "the 800-pound gorillas of pharmaceutical reimbursement." *Id.* at 71. Engaged by TPPs – a major category of the alleged victims here (*see* Compl. ¶ 2) – PBMs serve as "claims administrators, benefits advisors, and full-service providers . . . ." *Class Certification Opinion*, 230 F.R.D. at 71. The Court found that the presence of PBMs creates a wide dispersal of "commercial information regarding common negotiable contractual terms, such as rebates, discounts, audit rights, fee structure, penalties, risk assignment and other services . . . ." *Id.* at 71-72. <sup>1</sup> The Court also concluded that PBMs serve to "enhance competition" among parties,

<sup>1</sup> 

<sup>&</sup>lt;sup>1</sup> In its ruling on the merits in the MDL Class Action, this Court reaffirmed its decision with respect to SADs, stating, "[k]nowledge about the AWP of SADs was available in the industry largely because of the role of the PBMs, which represent TPPs in negotiating drug prices with pharmaceutical manufacturers to get discounts and rebates on SADs sold by pharmacies." *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 491 F. Supp. 2d 20, 39 (D. Mass. 2007) (hereinafter "*MDL Opinion*"). The Court also referred readers to its earlier class certification decision for a more detailed analysis of the role of PBMs in the SAD market. *Id.* at 40 n.19.

which in turn reduces the amount paid in reimbursements for SADs (assuming that reimbursements are even based on AWP). *See id.* at 72-73.

Just as this Court found that plaintiffs in the MDL Class Action could not account for the critical roles played by PBMs, Plaintiff's Complaint here suffers from the same failing. Plaintiff has not described how TPPs (and beneficiaries) reasonably could have been misled by AWPs for SADs when those entities and individuals benefited directly from the knowledge and bargaining power of PBMs – much less pled facts that would give rise to "a plausible entitlement to relief." See New England Carpenters Health Benefit Fund, 2008 WL 3919121, \*1. Rather, Plaintiff ignores the Court's prior findings with respect to SADs and PBMs and reiterates the same failed allegations advanced by MDL class plaintiffs. Plaintiff alleges that PBMs profit from the difference between the rate they reimburse pharmacies for drugs and the rate they charge TPPs for drugs,<sup>2</sup> and that manufacturers inflate AWPs to increase that profit to the PBMs. (Compl. ¶ 147). Because PBM contracts with pharmacies are confidential, Plaintiff alleges, TPPs are not informed of the reimbursement rate to pharmacies. (Compl. ¶ 149). Class plaintiffs similarly attempted to argue that manufacturers defrauded TPPs "by inflating AWPs to obtain favorable formulary placement" and pointed to a lack of transparency in PBM contracts. Class Certification Opinion, 230 F.R.D. at 72, 93. The Court found, citing independent expert Professor Berndt, "while the terms of a specific contract may be secret 'general knowledge concerning what is negotiable and what is the range of terms typically offered is widespread." *Id.* at 72. Under *Twombly*, it is simply not sufficient for Plaintiff to reiterate the same allegations that failed in the MDL class action proceeding and that are contrary to this Court's previous

<sup>2</sup> 

<sup>&</sup>lt;sup>2</sup> The Court expressly acknowledged this practice in the same opinion that denied class certification as to SADs. *See Class Certification Decision* at 73 ("The PBM pockets the difference between what it receives from its clients and what it pays the pharmacy.")

findings. Plaintiff has provided no plausible reason to think that TPPs (and indirectly beneficiaries) could have been deceived by the AWPs published for SADs.<sup>3</sup>

Plaintiff's theory with respect to brand SADs, where the prescribing decision is separated from the reimbursement process, makes even less sense. Plaintiff contends that manufacturers inflate AWPs to gain market share from competitors by inducing providers to prescribe one drug over others based on reimbursement "spreads." This motivation is entirely implausible – if not impossible – with respect to brand SADs. Manufacturers had no incentive to manipulate AWP with respect to brand SADs, because manufacturers cannot affect prescribing decisions on brand SADs through price reporting practices. As this Court has recognized, brand SADs are prescribed by doctors, but dispensed by pharmacies. For single-source, brand SADs, the doctor has no financial incentive to prescribe one drug over another, and the pharmacy cannot choose which drug to dispense. Legally, the pharmacy must dispense the prescription as written. MDL Opinion, 491 F. Supp. 2d at 71-72. With no logical incentive for manufacturers to inflate AWPs for single-source, brand SADs, Plaintiff's claims fall under the weight of Twombly's standard and should be dismissed pursuant to Rule 12(b)(6) without leave to replead.

# B. Plaintiff's Claims Regarding Multi-Source Drugs Reimbursed at a Single Rate are Equally Implausible and Should Also Be Dismissed.

Plaintiff's allegations of an AWP scheme make no sense in the context of multi-source drugs reimbursed based on MACs or medians, FULs, or any other uniform rates, rather than the drugs' own AWPs. Where all forms of a multi-source drug are reimbursed at a single rate, the

<sup>&</sup>lt;sup>3</sup> This Court has also noted that many TPPs paid for drugs themselves, thus providing "first hand knowledge of the acquisition costs for drugs." *Class Certification Opinion*, 230 F.R.D. at 95; *see also MDL Opinion*, 491 F. Supp. 2d at 40 ("[S]ome TPPs were vertically integrated, running staff model [HMOs] which purchased SADs. In this way, they learned that the AWP of the drug was not the price of acquisition.").

<sup>&</sup>lt;sup>4</sup> Again, Plaintiff makes a vague allegation that such AWPs are inflated to provide an illegal kickback to PBMs. (*See Compl.* ¶ 147-48). As noted above, that allegation cannot be squared with this Court's findings regarding PBMs and the SAD market. Moreover, though PBMs can set formularies, a PBM, like a pharmacist, cannot dispense anything but the drug prescribed by the physician unless the physician agrees otherwise.

manufacturers cannot compete for market share by manipulating reported prices. Plaintiff's conclusory allegations regarding collusive conduct by all multi-source drug manufacturers are implausible and, thus, do not cure fundamental deficiencies in Plaintiff's theory.

#### 1. Reimbursement of Multi-Source Drugs is Generally Not Based on AWP.

For the same reasons that this Court declined to certify a private class with respect to the reimbursement of multi-source drugs based on MACs, Plaintiff's claims relating to multi-source drugs are implausible here, in the abstract, without particularized allegations of concrete circumstances. As the Court knows, most multi-source drugs are reimbursed on the basis of MACs. This Court previously found that "a substantial portion of commercial payors have developed their own MAC lists and schedules that are proprietary and kept confidential." *Class Certification Opinion*, 230 F.R.D. at 74. For these reasons, a manufacturer's AWP may have nothing to do with a MAC on which reimbursement for its drug is based. Because MACs "var[y] from payor to payor, from contract to contract, and in some instances, from transaction to transaction," this Court ruled in the MDL Class Action that "generics will be considered only to the extent that . . . [reimbursement] is expressly predicated on AWP." *Id.* at 91.

The MDL class plaintiffs, in a tacit admission as to the implausibility of claims for multisource drugs in the private market (*i.e.* Class 3), did not even attempt to specify the extent to which reimbursement for generics was "expressly predicated on AWP," and instead abandoned claims for multi-source drugs in Class 3. Thus, in its ruling on the merits in the MDL Class Action, the Court noted that because of MACs, "TPP reimbursement for multi-source drugs is generally not calculated based on the drug's AWP" and, thus, plaintiffs did not assert a claim for damages with respect to TPP reimbursement (Class 3) of such drugs. *MDL Opinion*, 491 F. Supp. 2d at 39; *see also In re Pharmaceutical Industry Average Wholesale Price Litigation*, 478 F. Supp. 2d 164 (D. Mass. 2007) (dismissing claims brought by the State of California to the

extent that they related to drugs reimbursed on the basis of a state MAC or MAIC because the state did not "allege[] or establish[] a link between the alleged wrongdoing and the Maximum Allowable Ingredient Cost (MAIC) figure for drug reimbursement").

Despite the prevalence of MACs for multi-source drugs, Plaintiff, represented by the same lawyers that abandoned claims for multi-source drugs in the private market in the MDL Class Action, fails to specifically allege any payments or TPP reimbursement of multi-source drugs expressly predicated on AWP. Such claims fail under Rule 9(b) and this Court's prior rulings in other AWP proceedings. For this reason alone, Plaintiff's multi-source claims, at least with respect to the private market, should be dismissed.

2. Manufacturers Have No Incentive to Inflate Reported Prices for Multi-Source Drugs that are Reimbursed at a Single Rate.

More fundamentally, however, Plaintiff's allegations of fraud in the context of a single reimbursement rate plainly fail the *Twombly* test. Plaintiff makes conclusory statements in its Complaint that, because MACs, medians, FULs, or other single reimbursement rates are (sometimes) based on AWPs, a manufacturer has the incentive to inflate its AWPs so pharmacies will choose to dispense its drug over a competitor's. (*See* Compl. ¶¶ 152-56.) But Plaintiff's allegations are implausible, if not impossible, in light of the basic logic of reimbursement at a single rate, such as a MAC in the private market or median in the Medicare market. Because of the hundreds – if not thousands – of different, proprietary and confidential MAC lists that might be used by different TPPs and PBMs in the private market at any given time, it would be impossible for a manufacturer to keep track of – never mind try to manipulate – them.

Moreover, as the Court saw with respect to albuterol in the Track 1 trial, because of median-based reimbursement by Medicare, it is nearly impossible for any single manufacturer to have any impact on the Medicare reimbursement rates. *See In re Pharmaceutical Industry Average Wholesale Price Litigation*, 520 F.Supp.2d 267, 273 (D. Mass. 2007) (holding that Warrick's

price reporting practices for albuterol "did not cause Class 2 any damages because of the methodology for calculating Medicare reimbursement for multi-source drugs based on a median."); *see also* 8/27/07 Hr'g Tr. 24: 3-7 (Judge Saris noting, following the Track 1 trial, that "multi-source [claims in Medicare universe] ha[ve] an almost intractable causation issue around damages. There's that median.")

In addition to manufacturers' practical inability to manipulate MACs in the private market or medians in the Medicare market, Plaintiff's arguments are fatally flawed because competing for market share through AWP manipulation is impossible where all therapeutically equivalent drugs are reimbursed at the same single rate. A manufacturer cannot increase market share simply by inflating its AWPs where the provider is reimbursed the same amount regardless of which form of a multi-source drug it dispenses. Instead, the primary way for multi-source manufacturers to compete against each other for market share is through price competition and discounting. In other words, manufacturers of multi-source drugs have no incentive to engage in the fraud alleged by Plaintiff, if their therapeutically equivalent products are reimbursed at the same rate.

# 3. Allegations of Concerted Action by Multi-source Manufacturers are Implausible.

Plaintiff attempts to salvage its multi-source claims by alleging concerted action by manufacturers. Plaintiff asserts that "drug makers act in unison by elevating the AWP for all generic drugs, thereby inflating the amount of the reimbursement that occurs through Medicare ...." (Compl. ¶ 157.) In so doing, Plaintiff makes the same incomprehensible argument that its counsel made on behalf of class plaintiffs during the Track One bench trial – that is, generic manufacturers colluded to compete with one another. *See MDL Opinion*, 491 F. Supp. 2d at 98-99 (describing plaintiffs' theory and noting "that there are no claims or evidence of conspiracy or joint enterprise"). Plaintiff provides no explanation of why manufacturers agree to act "in

unison" only to then compete with their collaborators by undercutting their prices. It is precisely this kind of implausible, conclusory theory that the Supreme Court expressly rejected in *Twombly. See Twombly*, 127 S. Ct. at 1966 (holding that "a conclusory allegation of agreement at some unidentified point does not supply facts adequate to show illegality" and is insufficient to state a claim for conspiracy). In *Twombly*, the Supreme Court cautioned that courts should not allow plaintiffs to use a "largely groundless claim" to "take up the time of a number of other people." *Id.* This Court should heed that warning and dismiss Plaintiff's claims relating to multi-source drugs. Plaintiff's claims cannot survive a 12(b)(6) motion to dismiss under *Twombly*, and should be dismissed with prejudice and without leave to replead.

Even if Plaintiff's allegations regarding concerted action by multi-source manufacturers were sufficient to overcome the implausibility of their claims with respect to such drugs, which they are not, the Complaint still fails because such allegations, and others like them that vaguely allude to conspiracy or concerted action (*see* Compl. ¶¶ 7, 96, 102, 157), are not made with the particularity that Rule 9(b) requires in actions alleging conspiracy to defraud. "[I]n actions alleging conspiracy to defraud or conceal, the particularity requirements of Rule 9(b) must be met." *Hayduk* v. *Lanna*, 775 F.2d 441, 443 (1st Cir. 1985) (internal citations omitted); *Varney* v. *R.J. Reynolds Tobacco Co.*, 118 F.Supp.2d 63, 72 (D. Mass. 2000) (citing *Hayduk*, 775 F.2d at 443). To survive dismissal under Rule 9(b), Plaintiff would need to allege the who, what, where, and how of the purported conspiracy. For example, what specifically did defendants allegedly agree to do. Plaintiff's allegations fall far short of this mark.

# C. Claims Regarding Brand Drugs With Unremarkable WAC/AWP Spreads Should be Dismissed As Implausible.

Plaintiff alleges "fraud" with regard to any drug with an AWP that does not equal "the" actual average selling price for that drug without regard to the extent of the "spread" between

AWP and an average of marketplace transactions.<sup>5</sup> This allegation probably applies to every drug ever reimbursed in the State of Arizona, or for that matter, anywhere else in the United States. As this Court recognized in its Track One bench trial ruling, "at least since the start of the class period" government and industry insiders, such as TPPs, "came to understand that with respect to self-administered drugs, like pills, the AWP of the pill did not reflect the actual average price charged by the wholesalers to retail pharmacists." *MDL Opinion*, 491 F. Supp. 2d at 39. Rather, this Court found that it was widely known by industry participants that, for brand PADs and SADs, AWP "bore a formulaic relationship to WAC of a 20 to 25 percent markup" and "there was some discounting from WAC." *Id.* at 40. Accordingly, in its Track One bench trial ruling, this Court held that where spreads are typically below 30%, it finds "no liability." *Id.* at 108. In that context, the Court expressly rejected the "zero tolerance approach to liability" advanced by the class plaintiffs. *Id.* at 97.

Plaintiff's Complaint here alleges no facts that would make that exact same "zero tolerance" theory of liability any more plausible in this case than it was in the MDL Class Action. Plaintiff's Complaint does not explain (nor could it) how Plaintiff could possibly show that, for drugs with an unremarkable WAC/AWP spread, anyone was deceived. This lack of any factual context that makes the Complaint's allegations seem plausible on their face mandates dismissal under the standard announced by the Supreme Court in *Twombly* and Rule 12(b)(6). *See, e.g., Marrero-Gutierrez* v. *Molina*, 491 F.3d 1, 9-10 (1st Cir. 2007) (affirming dismissal because, as in *Twombly*, "without some further factual enhancement [the claim] stops short of the line between possibility and plausibility of entitlement to relief").

\_

<sup>&</sup>lt;sup>5</sup> So, for example, fraud is alleged with respect to the following drugs, for which Plaintiff alleges spreads that are less than or within the known 20-25% mark-up of AWP over WAC: Calcitrol (23%), Rocephin (23%), Immune Globulin (24%), Bleomycin Sulfate (20%), Methotetrate Sodium (24%), Depo-Testosterone (19.3%), Aclovir Sodium (25%), Amikacin Sulfate (20%) (*See* Compl.).

### D. Claims Regarding Transactions After the Enactment of the Medicare Modernization Act of 2003 Should be Dismissed.

Plaintiff's claims, apparently, are not limited to any specific time period. In fact, Plaintiff purports to assert claims continuing to the present day. (Compl. ¶ 520 ("The wrongful conduct alleged in this Amended Complaint occurs and continues to occur in the ordinary course of Defendants' business . . . . ").) This Court, however, addressing almost identical claims on behalf of consumers and TPPs in both the private and Medicare markets, ruled that the claims period ended "in 2003 when Congress passed the Medicare statute setting new reimbursement benchmarks." MDL Opinion, 491 F. Supp. 2d at 31. In its ruling on summary judgment in the MDL Class Action, the Court noted that the MMA and its "legislative history indicate that by 2003 . . . Congress clearly did understand AWP was different than average sales price and was not reflective of actual prices in the marketplace." In re Pharm. Indus. Average Wholesale Price Litig., 460 F. Supp. 2d 277, 288 (D. Mass. 2006). Thus, the Court granted summary judgment with respect to Medicare Part B drugs furnished after December 31, 2003. *Id.* In its MDL Opinion, the Court extended that ruling to transactions in the private market as well, holding that "[t]he class period ends the day the MMA went into effect." MDL Opinion, 491 F. Supp. 2d at 44. Plaintiff's Complaint does not allege any facts that would make it plausible that any different result should obtain in looking at TPPs and consumers in Arizona. If the legislative history and enactment of the MMA by the United States Congress provided sufficient information to Classes 2 and 3 in the MDL Class Action regarding AWP so as to bar claims after that date, the same result should obtain as to TPPs and consumers in Arizona.

# II. MANY OF THE CLAIMS ASSERTED BY PLAINTIFF HAVE BEEN FULLY ADJUDICATED AND/OR SETTLED AND RELEASED AND SHOULD BE DISMISSED.

As noted above, Plaintiff's Complaint asserts claims only on behalf of private citizens and other payors for violations of Arizona state law and does not assert claims on behalf of the

State of Arizona. (*See* Protective Order Mem.") at 1 (June 13, 2008) (Dkt. 5378).) Because "the claims of the State's private citizens" are the only claims underlying Plaintiff's Complaint, (*see id.* at 10),<sup>6</sup> this Court should dismiss the claims to the extent private citizens have released the underlying claims or the Court has otherwise adjudicated the underlying claims. *In re Baldwin-United Corp.*, 770 F.2d 328 (2d Cir. 1985).

### A. Most Claims Asserted By Plaintiff Against the MDL Track Two Defendants Are the Subject of the Track Two Settlement and Release.

On March 8, 2008, plaintiffs in the MDL Class Action, represented by Hagens Berman, who also represents Plaintiff in this action, and the MDL Track Two Defendants<sup>7</sup> filed a joint motion for preliminary approval of the Track Two Settlement. (Class Plaintiffs' and Track Two Defendants' Joint Motion for Entry of an Order Granting Preliminary Approval of the Track Two Settlement, Certifying Classes for Purposes of Settlement, Directing Notice to the Classes and Scheduling Fairness Hearing (March 7, 2008) (Dkt. 5131).) The Track Two Settlement, when finally approved, will release the claims of three broad classes of litigants:

- 1) Medicare Part B Co-Payment Class ("Class 1") All natural persons in the United States who, from January 1, 1991 through January 1, 2005 made, or incurred an obligation to make, any portion of a Medicare Part B co-payment for a Class Drug manufactured, marketed, sold, or distributed by a Released Company.
- 2) <u>Third-Party Payor MediGap Supplemental Insurance Class</u> ("<u>Class 2</u>") All Third Party Payors in the United States who, from January 1, 1991 through January 1, 2005, made, or incurred an obligation to make, reimbursements for any portion of a Medicare Part B co-payment for a Class Drug manufactured, marketed, sold, or distributed by a Released Company.

<sup>&</sup>lt;sup>6</sup> See also id. at 4 ([n]either the State nor the agencies . . . have claims in the case), 8 ("neither the government nor any governmental agency brings a claim).

<sup>&</sup>lt;sup>7</sup> The MDL Track Two Defendants who are also Defendants in this action include Abbott Laboratories, Amgen Inc., Aventis Pharmaceuticals, Inc., Aventis Behring, LLC, a/k/a ZLB Behring, LLC, Hoechst Marion Rouseel, Baxter Healthcare Corporation, Baxter International Inc., Bayer Corporation, Dey, Inc., Fujisawa Healthcare, Inc., Fujisawa USA, Inc., Immunex Corporation, Pharmacia Corporation, Pharmacia & Upjohn, Inc. Sicor, Inc., Gensia, Inc., Gensia Sicor Pharmaceuticals, Inc., and Watson Pharmaceuticals.

3) Consumer and Third-Party Payor Class For Payments Made Outside the Medicare Context ("Class 3") - All natural persons in the United States who made, or incurred an obligation to make, a non-Medicare Part B payment for a Class Drug manufactured, marketed, sold, or distributed by a Released Company, and all TPPs in the United States who made, or incurred an obligation to make, non-Medicare Part B reimbursements for a Class Drug manufactured, marketed, sold, or distributed by a Released Company, during the period from January 1, 1991, through March 1, 2008.

(Track Two Settlement and Release at 5-6, 15 (Mar. 7, 2008) (Dkt. 5133).)

As part of the Track Two Settlement, the consumer class members nationwide (including in Arizona) will release all claims related to: (a) "any drug price published by any commercial price reporting service;" (b) "any drug price . . . provided by any Released Company to any such commercial reporting service;" and (c) "any marketing activity relating to any such price, such as any reference to the difference between (1) a price paid and (2) any reported price or reimbursement rate based on such a reported price, that were or could have been alleged against any Released Company in any of the MDL Class Complaints" with respect to any "Class Drug"<sup>8</sup> manufactured, marketed, sold, or distributed by a Track Two Defendant. (Id. at 11-13, §§ II JJ, & LL.) The Track Two release contemplated by the TPP class members is even broader. Upon final approval of the settlement, TPPs nationwide (again, including in Arizona) agree to release all such claims with respect to "any drug manufactured, marketed, sold or distributed" by any Track Two Defendants. (Id. at 13, § NN (emphasis added).) On July 2, 2008, this Court entered its written order preliminarily approving that settlement. (Order Granting Preliminary Approval 17-18 (July 2, 2008) (Dkt. 5426).) Accordingly, upon final approval of the Track Two Settlement, claims that Plaintiff seeks to assert here will be released to the extent that they are based on alleged overpayments by TPPs in Arizona for any drugs manufactured and/or sold by

 $<sup>^{8}</sup>$  The "Class Drugs" comprise the drugs listed in Exhibit B to the Track Two Settlement. (See id. at 7 § II C & Ex. B.)

any MDL Track Two Defendant, or to the extent that they are based on alleged overpayments by consumers for any identified "Class Drug." The Complaint should be dismissed as to these settled claims pursuant to Rule 12(b)(6) for failing to state a claim, without prejudice pending final approval.

### B. Certain Claims Asserted by Plaintiff Against the MDL Track One Defendants Have Been Adjudicated and/or Settled and Released.

Similarly, adjudication and/or resolution of certain claims against the MDL Track One Defendants bar Plaintiff from re-asserting those same claims against the Track One Defendants in this case. In Track One, this Court certified nationwide classes of natural persons who made Medicare Part B co-payments for the "Subject Drugs" of AstraZeneca, Bristol-Meyers Squibb, GlaxoSmithKline, and Johnson & Johnson ("Class 1"). *See In re Pharmaceutical Industry Average Wholesale Price Litigation*, 233 F.R.D. 229, 230 (D. Mass. 2006) (hereinafter "*Class Certification Order*"). Class 1 thus encompassed claims by Medicare beneficiaries in Arizona asserted against certain of the Track One Defendants under the Arizona Consumer Fraud Statute – some of the exact same claims that Plaintiff now seeks to assert again in this action. 10

Certain of the Arizona consumer claims were subsequently settled as a part of the MDL proceeding. AstraZeneca and the MDL plaintiffs settled all Class 1 consumer class claims against AstraZeneca, its affiliates, successors, and predecessors, in law and equity, regarding Zoladex. (*See* Settlement Agreement and Release of AstraZeneca (May 21, 2007) (Dkt. 4227); Order Granting Preliminary Approval of the Astrazeneca Class 1 Settlement, Directing Notice to the Class and Scheduling a Fairness Hearing (Nov. 1, 2007) (Dkt. 4879).) Similarly, BMS and the MDL plaintiffs entered into a binding Memorandum of Understanding in which the parties

<sup>&</sup>lt;sup>9</sup> Classes 2 and 3 certified by the Court against the Track One Defendants were Massachusetts only classes. *Id.* at 231.

<sup>&</sup>lt;sup>10</sup> Although they were given an adequate opportunity to do so, the MDL class plaintiffs failed to propose "any adequate and typical [class] representative" for the Schering subject drugs and, thus, the Court "decline[d] to certify a class of [natural] persons who made co-payments for drugs manufactured by the Schering-Plough Group." *Id.* 

agreed to settle all consumer class claims (the "BMS MOU"). The BMS MOU expands the scope of the settlement to cover all claims "alleged or that could have been alleged in the AWP MDL against defendants BMS, Oncology Therapeutics Network Corporation and Apothecon, Inc." by "all individual consumers on a nationwide basis and any such person who was coinsured under Medicare Part B with a Medigap insurer, employer- or union-sponsored health plan, or any other third-party payer for any portion of a payment for one or more of the BMS drugs at issue." Again, these settled claims should be dismissed for failure to state a claim without prejudice pending final approval.

With regard to the Class 1 consumer claims again Johnson & Johnson, Centocor, Inc., and Ortho Biotech Products, LP, this Court entered a final judgment in their favor and against consumers nationwide because it found, after trial, that the spreads on their subject drugs (Procrit and Remicade) were not unfair or misleading. *MDL Opinion*, 491 F. Supp. 2d at 31, 102-103; *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 01- CV-12257-PBS, Findings and Order on Mot. of Track 1 Defs. for the Entry of Judgment Pursuant to Fed. R. of Civ. P. 54(b) (hereinafter "*Order Entering 54(b) Judgment*") (Nov. 20, 2007) (Dkt. 4896-3). Thus, the claims of Arizona consumers as they relate to these drugs have been fully adjudicated, and cannot and should not be re-litigated in this action.

Although Class 1 was not certified as to Schering-Plough and Warrick, *Class Certification Order*, 233 F.R.D. at 230, after trial of the Classes 2 and 3 claims, this Court entered final judgment in favor of Schering-Plough, Schering, and Warrick as to TPP and other claims, finding on the merits that Schering's spreads were not unlawful and Warrick's conduct

Presently pending before this Court (and advanced by the same counsel as is bringing this case) is a motion to certify nationwide classes of TPPs as against AstraZeneca and BMS. (Plts.' Mot. to Certify Nationwide Classes 2 and 3 Against Defs. AstraZeneca and BMS (Nov. 21, 2007) (Dkt. 4902)). If that motion is allowed, there would be even further overlap between this case and the MDL proceeding.

As GSK is not named as a defendant in this case, the details of its subsequent nationwide settlement with the Class 1 consumers are not relevant for purposes of this motion.

had no effect on the amount of Medicare co-payments and thus had not caused any damages. See Order Entering 54(b) Judgment, at 5, 7 & 11; MDL Opinion, 491 F. Supp. 2d at 108. In doing so, this Court foreclosed the re-litigation of consumer class claims against Schering-Plough, Schering, and Warrick, including such claims brought by Arizona consumers. See, e.g., In re Bridgestone/Firestone, Inc. Tire Prods. Liab. Litig., 333 F.3d 763 (7th Cir. 2003) (holding that the denial of class certification has collateral estoppel effects even for unnamed class members); Lee v. Criterion Ins. Co., 659 F. Supp. 813, 823 (S.D. Ga. 1987)(citing Deposit Guar. Nat'l Bank, Jackson, Miss. v. Roper, 445 U.S. 326, 336 (1980), for the proposition that the denial of class certification stands as an adjudication of one of the issues litigated for all those litigants who had a full and fair opportunity to participate in the class certification process, and noting the Supreme Court's statement "with reference to the public policy against subjecting parties to repetitive litigation over an issue that has once been resolved by a court of competent jurisdiction" as a basis for its ruling). As the claims being advanced by Arizona in this action against Schering-Plough and Warrick are effectively consumer class claims being brought derivatively on behalf of a subset of the MDL consumer class, they have already been fully adjudicated and, therefore, should be dismissed. See id.

The same is true more broadly of Arizona's claims with respect to <u>all</u> self-administered drugs. As noted in Section I.A of this memorandum, this Court in the MDL Class Action declined to certify a class with respect to SAD-based "AWP fraud" claims. *Class Certification Opinion*, 230 F.R.D. at 95-96. Nonetheless, the MDL class litigants (including Arizona consumers and TPPs) had a full and fair opportunity to litigate the issue in that forum. Accordingly, they should be barred from effectively re-litigating the exact same issue in this case. *See, e.g., Bridgestone/Firestone*, 333 F.3d at 763. If Arizona is permitted to bring claims on their behalf here, that is precisely what will occur. As discussed more fully in the next

Section, to the extent Plaintiff's claims are derivative of ones that were litigated and decided in the MDL, Arizona should be barred from bringing them simply because they are now being asserted in a slightly different form.

# C. Plaintiff's Claims that Are Derivative of Claims Covered by MDL Class Action Settlements or Judgments Should be Dismissed.

The Court should dismiss all claims asserted in Plaintiff's Complaint that derive from claims by Arizona consumers and TPPs that have been settled and/or adjudicated. The Second Circuit's decision in *In re Baldwin-United Corp.*, 770 F.2d 328 (2d Cir. 1985), is instructive on this point. There, thirty-one states, including Arizona, that were not parties to a federal court settlement of an MDL consolidated class action against a number of securities broker-dealers, appealed an injunction issued by the federal district court barring them from bringing state law actions against those same broker-dealers for the same set of facts that were the subject of the settlement, where the damages sought by the states were intended to be paid over to persons who were parties to the settlement agreement. *Id.* at 334, 337. The Second Circuit noted that the states' objective, similar to the apparent objective of Plaintiff here, was "to enforce state laws authorizing them in their representative capacities to seek restitution and monetary recovery from the defendants to be paid over to those of the states' citizens who are plaintiffs in the consolidated class actions." *Id.* at 332-33.

The Second Circuit upheld the injunction against the states noting that, if the states were allowed to pursue such actions based on the claims of its citizens who had settled their own claims, "the finality of virtually any class action involving pendent state claims could be defeated by subsequent suits brought by the states asserting rights derivative of those released by the class members." *Id.* at 336. The court explained:

no defendant in the consolidated federal actions in the present case could reasonably be expected to consummate a settlement of those claims if their claims could be reasserted under state laws, whether by states on behalf of the plaintiffs or by anyone else, seeking recovery of money to be paid to the plaintiffs. Whether a state represented itself to be acting as a "sovereign" in such a suit or described its prayer as one for "restitution" or a "penalty" would make no difference if the recovery sought by the state was to be paid over to the plaintiffs.

*Id.* at 336-37. Even where the state asserts claims or theories "not available to private plaintiffs that enable a given state to bring proceedings seeking restitutionary damages for the benefit of certain of its citizens," the Second Circuit concluded that the claim is still "representative" and "essentially derivative" of the citizen's claims because "any recovery would not go to the state but [class members] in the federal action, who are the real parties in interest." *Id.* at 341-42.

The same reasoning supports dismissal of Plaintiff's claims here that are representative and derivative of the claims of class members from the MDL Class Action who have settled or against whom judgments have already been entered. If a federal district court can take the extraordinary step of enjoining states from even pursuing such actions seeking restitution for their citizens who are members of a settlement class, certainly this Court, with another such class action properly pending before it involving overlapping claims, can take the modest step, necessary to protect its own jurisdiction in the earlier filed class case, of dismissing claims brought by a state on behalf of citizens and TPPs – some of whom are also members of the class in the MDL Class Action. At a minimum, this Court can and should dismiss those claims covered by the Track Two Settlement, the Track One Settlements, and the judgments entered in favor of Johnson & Johnson, and Schering-Plough and Warrick. It should also protect its prior decision with regard to self-administered drug claims. Accordingly, as summarized in Exhibit 1, this Court should dismiss Plaintiff's claims to the extent they are based on (i) alleged overpayments by TPPs in Arizona for drugs manufactured and/or sold by Track Two Defendants, (ii) alleged overpayments by Arizona consumers for any identified "Class Drug" manufactured and/or sold by the Track Two Defendants, (iii) alleged overpayments by Arizona

Medicare beneficiaries who purportedly overpaid for the "Subject Drugs"<sup>12</sup> sold by Track One Defendants AstraZeneca, Bristol Meyers Squibb, Johnson & Johnson, and Schering-Plough, Schering, and Warrick, and (iv) alleged overpayments by Arizona TPPs and consumers for all self-administered drugs.

#### III. THE COURT SHOULD DISMISS THE PLAINTIFF'S CLAIMS AS UNTIMELY

Under Arizona law, any claim based "upon liability created by statute" must "be commenced and prosecuted within one year after the cause of action accrues, and not afterward." A.R.S. § 12-541. Thus, the statute of limitations for consumer fraud claims brought pursuant to Section 44-1522 of the Arizona Consumer Fraud Act is one year. See Alaface v. Nat'l Inv. Co., 892 P.2d 1375, 1380 (Ariz. App. Div. 1 1995) ("As a liability created by statute, a consumer fraud action must be initiated within one year after the action accrues."). While Arizona law generally exempts the State from this limitations period, see A.R.S. § 12-510; Tucson Unified Sch. Dist. v. Owens-Corning Fiberglass Corp., 174 Ariz. 336 (Ariz. 1993), here, Plaintiff purports to vindicate the rights of Arizona citizens and payors – the real parties in interest. Because Plaintiff's claims here are derivative of the claims of those private citizens, as discussed above, the one-year limitations period should apply. See Trimble v. Am. Sav. Life Ins. Co., 733 P.2d 1131 (Ariz. App. 1986); Diamond Benefits Life Ins. Co. v. Resolute Holdings, 907 P.2d 63 (Ariz. 1995) (applying Section 12-510 in circumstances where "in effect ... the state is a real party in interest"); cf. Baldwin-United, 770 F.2d at 336-37, 341-42 (even where the state purports to act in a sovereign capacity, its claims are still representative and derivative of the claims of its citizens where the recovery would flow to those citizens who are the "real parties in interest"). 13

<sup>&</sup>lt;sup>12</sup> See Class Certification Order, 233 F.R.D. at 232-34.

<sup>&</sup>lt;sup>13</sup> In *Tucson*, the Arizona Supreme Court held that a school district suing for asbestos removal from schools was entitled to the protection of A.R.S. § 12-510. The Court held that a school district was properly deemed the "State" for purposes of A.R.S. § 12-510 and further held that the school district was entitled to the protection of A.R.S. § 12-510 regardless of whether it could be considered to be acting in a "private" capacity as the "owner" of the schools.

Applying the one-year statute of limitations in A.R.S. § 12-541, Plaintiff's claims are time barred. The original complaint in this action was filed on December 6, 2005, (see Compl. (Dec. 6, 2005)), and thus meets the one year statute of limitations period only if the claims at issue accrued on or after December 6, 2004. Under the "discovery rule," a consumer fraud claim accrues when the defrauded party discovers or, with reasonable diligence, should have discovered the fraud. See Alaface, 892 P.2d at 1380. In the MDL Class Action presenting almost identical claims on behalf of consumers and TPPs, this Court found that sufficient publicly available information regarding the nature of AWP existed as of August 1997 so as to put plaintiffs on inquiry notice of the facts that were the basis of their claims. MDL Opinion, 491 F. Supp. 2d at 75-80. Moreover, as discussed above in Section I.D, the Court cut off liability completely as of December 2003 because, by the time the Medicare Modernization Act was enacted on December 8, 2003, Congress and the market properly understood that AWP was not reflective of average acquisition costs. See id. at 31. As the claims at issue here are very similar to those addressed in the MDL Class Action, the underlying claim in this action undoubtedly accrued long before December 6, 2004 (indeed, on December 8, 2003, at the very latest) and, as such, is untimely.

### IV. PLAINTIFF HAS FAILED TO MEET BASIC PLEADING REQUIREMENTS ALREADY SET FORTH BY THIS COURT.

Plaintiff has also failed to plead its (implausible) claims with the particularity required by Federal Rule of Civil Procedure 9(b), which applies to Plaintiff's allegations and requires that the circumstances constituting that alleged scheme be pled with particularity. *See In re Average*Wholesale Price Litig., 2007 WL 1051642, at \*14 (D. Mass. Apr. 2, 2007) (hereinafter "New York Counties"); In re Pharmaceutical Industry Average Wholesale Price Litig., 263 F. Supp. 2d

The circumstances here are very different. The State's claims are being brought on behalf of a small, distinct group of private individuals and entities, who have already sued themselves.

172, 194 (D. Mass. 2003) ("*Pharm I*"); see also New England Data Servs., Inc. v. Becher, 829 F.2d 286, 289 (1st Cir. 1987). Plaintiff's claims are brought under the Arizona Consumer Fraud Act ("ACFA"), and it is beyond dispute that "[t]he particularity requirement of Rule 9(b) applies to ACFA claims." *Beshears* v. *Provident Life and Acc. Ins. Co.*, 2007 WL 1438738, \*3 (D. Ariz. 2007) (citing *Williamson* v. *Allstate Ins. Co.*, 204 F.R.D. 641, 643-44 (D. Ariz. 2001)).

This Court has previously ruled that compliance with Rule 9(b) requires that the complaint allege with respect to each defendant<sup>14</sup> at least: (1) the specific drug(s) purchased; (2) the allegedly fraudulent AWP(s) for each such drug; (3) the purchaser(s) or reimburser(s) for the drug(s); and (4) for each subject drug, a "good faith estimate of an 'actual' market price from which the spread may be calculated' or the alleged spread itself." *See New York Counties*, 2007 WL 1051642, at \*14; *see also In re Pharmaceutical Industry Average Wholesale Price Litig.*, 2004 WL 2387125, at \*4 (D. Mass. 2004). Here, Plaintiff has failed to fulfill the third and fourth requirements.

Plaintiff has not identified with particularity any entity or person that was injured as a result of the alleged scheme. This Court has ruled previously that an AWP plaintiff must "clearly and concisely allege with respect to each defendant [among other things] . . . the name of the specific plaintiff(s) that purchased the drug." *Pharm I*, 263 F. Supp. 2d at 194. Pursuant to Rule 9(b), Defendants are entitled to know the identity of the allegedly injured party or parties with particularity. This requirement of particularity of the allegedly injured party is especially important here where the rulings, settlements, and judgments discussed above affect the viability of many of the claims that Plaintiff seeks to pursue. Yet Plaintiff's Complaint contains only generalized allegations about individuals and entities. (*See* Compl. ¶¶ 1-2, 509.) As the Court is

<sup>&</sup>lt;sup>14</sup> Plaintiff's choice to pursue claims against multiple defendants does not excuse it from Rule 9(b)'s particularity requirements. "The sufficiency of a pleading pursuant to Rule 9(b) must be decided as to <u>each</u> defendant in the action." *Kilmartin, Jr.* v. *H.C. Wainwright & Co.*, 637 F. Supp. 938, 942 (D. Mass. 1986) (emphasis added).

well aware from its considerable experience in these cases, whether any person or third-party payor actually paid on the basis of AWP for any given drug is often difficult to ascertain.

Plaintiff also has not provided particularized information about the allegedly fraudulent spreads that it says existed with respect to each of the 1,000-plus drugs listed in the Complaint. This Court has held that an AWP Plaintiff must provide – for each subject drug – either a "goodfaith estimate of an 'actual' market price" from which a "spread" can be calculated or the allegedly fraudulent spread itself. New York Counties, 2007 WL 1051642, at \*14. Despite this requirement, Plaintiff merely attaches to the Complaint in "Appendix A" a list containing more than a thousand drugs and the corresponding AWPs for those drugs. The list contains neither "actual market" prices nor any spreads. 15 The Complaint, therefore, is grossly deficient under this Court's prior orders. These failings compel dismissal of the Complaint.

#### **CONCLUSION**

For all the foregoing reasons, Defendants' Motion to Dismiss should be GRANTED.

Schering-Plough Corporation and Warrick Pharmaceuticals Corporation By their attorneys,

/s/ John P. Bueker

John T. Montgomery (BBO#352220) John P. Bueker (BBO #636435) Daniel J. Bennett (BBO #663324) Ropes & Gray LLP One International Place Boston, Massachusetts 02110-2624

(617) 951-7000

Dated: September 19, 2008

<sup>&</sup>lt;sup>15</sup> The body of the Complaint contains a smattering of spreads for a few drugs for some Defendants, but more than a thousand additional drugs appear in the Appendix without such information.

#### **CERTIFICATE OF SERVICE**

I hereby certify that on September 19, 2008, I caused a true and correct copy of the foregoing to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

/s/ Daniel J. Bennett
Daniel J. Bennett